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REMARKS

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Claims 1-4, 6-17, and 19-30 are pending. Claims ~~1-12, 19, 27, 28, and 30~~ have been amended. Claim 31 has been added. Support for the amendments are found in the Specification as filed at least in paragraphs 0006, 0009, 0014, 0015, 0016, 0028, and 0035. No new matter has been added.

Applicant respectfully submits that the amended claims are now patentable over the references of record, specifically Savage et al. (U.S. Patent No. 5,979,453 hereinafter "Savage"), Behl et al. (U.S. Patent No. 6,212,433 hereinafter "Behl"), Edwards et al. (U.S. Patent No. 5,935,123 hereinafter "Edwards"), Burbank et al. (U.S. Patent No. 6,254,601 hereinafter "Burbank"), Schmaltz et al. (U.S. Patent No. 6,190,383 hereinafter "Schmaltz"), and Moorman et al. (U.S. Patent No. 6,355,033 hereinafter "Moorman"), alone or in combination.

Claims 1, 2, 6-13, 16, 19-23, and 25-30 are rejected under 35 U.S.C. §103(a) as being unpatentable over Savage in view of Behl and further in view of Edwards. In rejecting the claims, the Examiner writes in part:

Savage and Behl neglect to disclose complete insertion of the electrodes into the targeted tumor.

Edwards . . . discloses an analogous tumor treatment system and method in which the device electrode is inserted completely within the targeted tumor (154) as depicted in figure 15.

[I]t would have been obvious to one of ordinary skill in the art to modify Savage in view of Behl and further in view of Edwards by including a plurality of deployable electrode arms as a design expedient as well as complete insertion of the device electrode into the targeted tumor. The motivation would be to uniformly generate heat throughout a desired target tissue volume through the use of symmetrically spaced apart electrodes as disclosed in Behl column 1 lines 36-39. The nexus between Savage and Behl is found in Behl col. 4:20-24 and 37-47. Behl's "two-step method" in col. 4:43-44 includes as a first step targeting blood flow to the targeted tumor prior to targeting the tumor itself. This first step is analogous to Savage's disclosed protocol. The motivation for complete insertion of the electrode into the targeted tumor would be to minimize damage of healthy peripheral tissue due to the heat generated by the electrode.

Applicants submit that Edwards is not properly combinable with Savage and Behl which teach away from complete insertion of an electrode within a tumor.

Savage discloses that "tumor shrinkage can be preferentially induced by destroying the tumor's blood supply, which is generally located on the periphery, *rather than* by targeting the

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bulk of the fibroid. Physicians . . . use the needles to ring the tumor with cores of coagulation.” (Savage, col.1, ll.43-48). Such a procedure causes significant damage to the normal surrounding muscle and tissue. Savage then explicitly discloses that the “present invention provides electrosurgical needles, needle systems, and methods for their use which will allow the surgeon to target a tumor’s blood supply.” (Savage, col.2, ll.22-24). Savage discloses a “needle system 40” including a “Doppler ultrasound image system 46” to provide “an image of bloodflow.” (Savage, col.5, ll.38-44, emphasis added). Savage further discloses that “the sheath transducer permits the surgeon to target the blood supply of a fibroid, prostatic adenoma, or other tumor by placing the end of the sheath against adjacent tissues.” (Savage, col.4, ll.32-35). Thus, Savage discloses heating tissue adjacent a tumor to target the blood supply of a tumor and not the bulk of the tumor itself. Accordingly, Savage teaches away from insertion of a needle completely within the tumor.

Behl does not remedy the deficiencies of Savage noted above. As noted by the Examiner, Behl discloses a step to “first necrose tissue at or near a distal periphery of the target region so that the vasculature is at least partly destroyed in order to reduce the blood flow into . . . the target region.” (Behl, col.4, ll.39-42). Behl further discloses that the electrode array is “powered first in order to necrose tissue at a boundary of the target region and inhibit blood flow into the region.” (Behl, col.8, ll.54-56). As shown in FIG. 6C, Behl discloses that deployed electrodes 32 are placed in tissue adjacent the tumor to necrose a boundary region B1 and thereby inhibit blood flow. (Behl, col.11, ll.11-14; FIG. 6A-6C). Thus, Savage modified in view of Behl still targets the blood supply of a tumor by heating tissue adjacent a tumor with a plurality of electrodes. Accordingly, Savage in view of Behl still teaches away from insertion of the electrodes completely within the tumor.

Edwards is not properly combinable with Savage and Behl because such a combination destroys the intent, purpose, and function of Savage and Behl to target the blood supply of the tumor, which requires heating of tissue adjacent the tumor as taught in Savage and Behl. Edwards does not disclose or suggest targeting a tumor’s blood supply or a peripheral area adjacent the tumor to target the blood supply. Instead, Edwards discloses a single electrode for targeting the bulk of the tumor itself. Thus, Savage modified in view of Behl is not properly combinable with Edwards to show insertion of electrodes completely within the tumor because such a combination would destroy the intended function of Savage and Behl.

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In contrast, Claims 1 and 12 recite "deploying the plurality of electrodes within a pelvic tumor to avoid contact with normal tissue outside of the pelvic tumor" and "confirming placement of the plurality of electrodes completely within the pelvic tumor with . . . laparoscope and . . . imaging device." Therefore, because Savage and Behl are not properly combinable with Edwards, Claims 1 and 12 are patentable over Savage in view of Behl and further in view of Edwards.

Claims 2 and 6-11 are dependent on Claim 1 and contain additional limitations that further distinguish them from Savage in view of Behl and further in view of Edwards. Therefore, Claims 2 and 6-11 are allowable for at least the same reasons provided above for Claim 1.

Claims 13, 16, 19-23, and 25-26 are dependent on Claim 12 and contain additional limitations that further distinguish them from Savage in view of Behl and further in view of Edwards. Therefore, Claims 13, 16, 19-23, and 25-26 are allowable for at least the same reasons provided above for Claim 12.

Savage, Behl, Edwards, Burbank, Schmaltz, and Moorman, alone or in combination, also fail to disclose or suggest a system including "an ablation device for insertion into a pelvic region of a patient, wherein the ablation device includes a tip and a plurality of electrodes deployable from the tip; . . . a laparoscope for insertion of the plurality of electrodes within a pelvic tumor of the patient to avoid contact with normal tissue outside of the pelvic tumor; and an intra-abdominal ultrasound device for observing a location of the plurality of electrodes completely within the pelvic tumor of the patient, wherein the laparoscope and the intra-abdominal ultrasound device are connected to at least one monitor, the at least one monitor being located along a first side of an operating table, and wherein the energy source and the intra-abdominal ultrasound device are located adjacent the at least one monitor along the first side of the operating table," as recited in Claim 27. Applicant is not aware of such a combination of elements having been utilized in gynecology or surgery in the pelvic area. Such a combination allows for the accurate ablation of smaller tumors and accordingly more comprehensive ablation of tumors without damage to surrounding healthy tissue.

Claims 28-29 are dependent on Claim 27 and contain additional limitations that further distinguish them from Savage in view of Behl and further in view of Edwards. Therefore, Claims 28-29 are allowable for at least the same reasons provided above for Claim 27.

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Claim 30 recites "inserting a tip of an ablation device including a plurality of electrodes deployable from the tip into a single puncture site in a pelvic region, the puncture site being approximately 1 mm to 2 mm in diameter; deploying the plurality of electrodes within at least one pelvic tumor to avoid contact with normal tissue outside of the at least one pelvic tumor, the at least one pelvic tumor having a diameter of at least 1 cm; confirming placement of the plurality of electrodes completely within the at least one pelvic tumor with a laparoscope and an imaging device; delivering RF energy to the ablation device; and heating the at least one pelvic tumor to a temperature between approximately 85 °C and approximately 100 °C for between approximately 7 and 14 minutes, wherein from the single puncture site substantially all of the at least one pelvic tumor is ablated."

The present invention advantageously allows for comprehensive ablation of a tumor area with only a single puncture as opposed to bipolar methods ablating tissue between two separate needles. A device including two separate needles for bipolar mode ablation disadvantageously causes multiple punctures upon entering the organ to be treated and only ablates tissue between the needles, thus usually requiring multiple passes for ablation of the entire tumor area. Savage in view of Behl and further in view of Edwards disadvantageously disclose multiple punctures and/or passes for shrinking a tumor. Accordingly, because Savage and Behl are not properly combinable with Edwards and even if combined, the references do not disclose all the limitations of Claim 30, Claim 30 is patentable over Savage in view of Behl and further in view of Edwards.

Claims 3, 4 and 14-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over Savage in view of Behl and further in view of Edwards and further in view of Burbank.

Burbank discloses "occluding uterine arteries." (Burbank, Abstract). Thus, Burbank does not remedy the deficiencies of Savage noted above with regard to Claims 1 and 12. Claims 3-4 and 14-15 are dependent on Claims 1 and 12, respectively, and contain additional limitations that further distinguish them from Savage in view of Burbank. Therefore, Claims 3-4 and 14-15 are allowable for at least the same reasons provided above for Claims 1 and 12, respectively.

Claim 17 is rejected under 35 U.S.C. §103(a) as being unpatentable over Savage in view of Behl and further in view of Edwards and further in view of Burbank and further in view of Schmaltz.

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Schmaltz does not remedy the deficiencies of Savage in view of Burbank noted above with regard to Claim 12. Claim 17 is dependent on Claim 12 and contains additional limitations that further distinguish it from Savage in view of Burbank and further in view of Schmaltz. Therefore, Claim 17 is allowable for at least the same reasons provided above for Claim 12.

Claim 24 is rejected under 35 U.S.C. §103(a) as being unpatentable over Savage in view of Behl and further in view of Edwards and further in view of Moorman.

Moorman does not remedy the deficiencies of Savage noted above with regard to Claim 12. Claim 24 is dependent on Claim 12 and contains additional limitations that further distinguish it from Savage in view of Moorman. Therefore, Claim 24 is allowable for at least the same reasons provided above for Claim 12.

New Claim

Claim 31 is dependent on Claim 30 and contains contain additional limitations that further distinguish it from Savage in view of Behl and further in view of Edwards. Therefore, Claim 31 is allowable for at least the same reasons provided above for Claim 30.

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For the foregoing reasons, Applicant believes pending Claims 1-4, 6-17, and 19-31 are allowable, and a notice of allowance is respectfully requested. If the Examiner has any questions or concerns, the Examiner is hereby requested to telephone Applicant's Attorney at (949) 752-7040.

I hereby certify that this correspondence is being transmitted via facsimile to telephone number (703)746-7013 addressed to: Mail Stop Non-Fee Amendment, Commissioner for Patents, Alexandria, VA 22313-1450, on September 4, 2003.

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9/4/03
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